

ROJAN[®] MTD

One Step Methadone Test Strip Package Insert

REF-R1104

English

A rapid, one step test for the qualitative detection of Methadone in human urine. For healthcare professionals including professionals at point of care sites. For *in vitro* diagnostic use only.

INTENDED USE

The MTD One Step Methadone Test Strip is a lateral flow chromatographic immunoassay for the detection of Methadone in human urine.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Methadone is a narcotic pain reliever for medium to severe pain. It is also used in the treatment of heroin (opiate dependence: Vicodin, Percocet, Morphine, etc.) addiction. Oral Methadone is very different than IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.¹

The MTD One Step Methadone Test Strip is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methadone in urine. The MTD One Step Methadone Test Strip yields a positive result when the Methadone in urine exceeds 300 ng/mL.

PRINCIPLE

The MTD One Step Methadone Test Strip is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Methadone, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody-coated particles in the test strip. The antibody-coated particles will then be captured by immobilized Methadone conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Methadone level exceeds 300 ng/mL because it will saturate all the

binding sites of anti-Methadone antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration lower than the cut-off will generate a line in the test line region.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test strip contains mouse monoclonal anti-Methadone antibody-coupled particles and Methadone-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test strip should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test strips
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer
- External Controls

DIRECTIONS FOR USE

Allow the test strip, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove

the test strip from the sealed pouch and use it as soon as possible.

2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 5 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.

3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

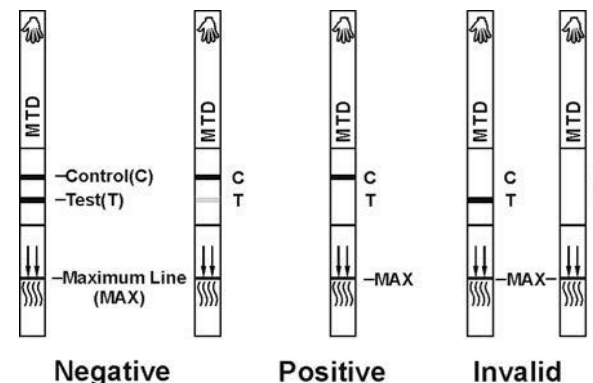
(Please refer to illustration below)

NEGATIVE:* **Two lines appear.** One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Methadone concentration is below the detectable level (300 ng/mL).

* **NOTE:** The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: **One red line appears in the control region (C).** No line appears in the test region (T). This positive result indicates that the Methadone concentration exceeds the detectable level (300 ng/mL).

INVALID: **Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test strip. If the problem persists, discontinue using the lot immediately and contact your local distributor.



QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The MTD One Step Methadone Test Strip provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) are the preferred

confirmatory methods.^{2,3}

2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.

3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.

4. A Positive Result indicates presence of the drug or its metabolites but does not indicate level or intoxication, administration route or concentration in urine.

5. A Negative Result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.

6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the MTD One Step Methadone Test Strip and a leading commercially available MTD rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing.

Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

When compared to GC/MS at the cut-off of 300 ng/mL, the following results were tabulated:

Method	GC/MS			Total Result
	Result	Positive	Negative	
	MTD One step test strip	Positive	122	
	Negative	1	167	168

Method	Other MTD Rapid Test		Total Result	
	Result	Positive		Negative
	MTD One step test strip	Positive		132
	Negative	0	168	168
Total result		132	168	300
%Agreement with this commercial kit		>99%	>99%	>99%
Total result		123	177	300
%Agreement with GC/MS Analysis		%99	%94	%96

Analytical Sensitivity

A drug-free urine pool was spiked with Methadone at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL and 450 ng/mL. The result demonstrates 97% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Methadone Conc. (ng/ml)	Percent of cutoff	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	29	1
225	-25%	30	24	6
300	Cutoff	30	21	9
375	25%	30	2	28
450	50%	30	0	30

Specificity

The following table lists compounds that are positively detected in urine by the MTD One Step Methadone Test Strip at 5 minutes.

Compound	Concentration (ng/mL)
Methadone	300
Doxylamine	50,000

Precision

A study was conducted at 3 physician's offices by untrained operators using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Methadone, 25% Methadone above and below the cut-off and 50% Methadone above and below the 300 ng/mL cut-off was provided to each site. The following results were tabulated:

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with Methadone to 150 ng/mL and 450 ng/mL respectively. The MTD One Step Methadone Test Strip was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not

Methadone Conc. (ng/ml)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	12	3	15	0	15	0
225	15	8	7	14	1	15	0
375	15	0	15	0	15	1	14
450	15	1	14	0	15	0	15

affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Methadone to ng/mL and ng/mL. The spiked, pH-adjusted urine was tested with the MTD One Step Methadone Test Strip in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methadone positive urine. The following compounds show no cross reactivity when tested with the MTD One Step Methadone Test Strip at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Estrone-3-sulfate	Oxymetazoline
Acetophenetidin	Ethyl-p-aminobenzoate	Papaverine
N-Acetylprocainamide	Fenoprofen	Penicillin-G
Acetylsalicylic acid	Furosemide	Pentazocine hydrochloride
Aminopyrine	Gentisic acid	Pentobarbital
Amitypyline	Hemoglobin	Perphenazine
Amobarbital	Hydralazine	Phencyclidine
Amoxicillin	Hydrochlorothiazide	Phenelzine
Ampicillin	Hydrocodone	Phenobarbital
L-Ascorbic acid	Hydrocortisone	Phentermine
DL-Amphetamine sulfate	O-Hydroxyhippuric acid	Trans-2-phenylcyclopropylamine hydrochloride
Apomorphine	p-Hydroxyamphetamine	L-Phenylephrine
Aspartame	p-Hydroxy-methamphetamine	β-Phenylethylamine
Atropine	3-Hydroxytyramine	Phenylpropanolamine
Benzilic acid	Ibuprofen	Prednisolone
Benzoic acid	Imipramine	Prednisone
Benzoylecgonine	Iproniazid	Procaine
Benzphetamine	(±) - Isoproterenol	Promazine
Bilirubin	Isoxsuprine	Promethazine
(±) - Brompheniramine	Ketamine	DL-Propriolol
Caffeine	Ketoprofen	D-Propoxyphene
Cannabidiol	Labetalol	D-Pseudoephedrine
Cannabinol		

Chloralhydrate	Levorphanol	Quinacrine
Chloramphenicol	Loperamide	Quinidine
Chlorothiazide	Mephentermine	Quinine
(±) - Chlorpheniramine	Meprotriline	Ranitidine
Chlorpromazine	Meperidine	Salicylic acid
Chloroquine	Meprobamate	Secobarbital
Cholesterol	Methamphetamine	Serotonin
Clomipramine	Methoxyphenamine	Sulfamethazine
Clonidine	(±) - 3,4-Methylenedioxy-amphetamine hydrochloride	Sulindac
Cocacethylene	(±) - 3,4-Methylenedioxy-methamphetamine hydrochloride	Temazepam
Cocaine hydrochloride	Morphine-3-β-D-glucuronide	Tetracycline
Codeine	Morphine Sulfate	Tetrahydrocortisone, 3-acetate
Cortisone	Naloxone	Tetrahydrocortisone 3-(β-D-glucuronide)
(-) Cotinine	Nalidixic acid	Tetrahydrozoline
Creatinine	Naltrexone	Thebaine
Deoxycorticosterone	Naproxen	Thiamine
Dextromethorphan	Niacinamide	Thionidazine
Diazepam	Nifedipine	DL-Tyrosine
Diclofenac	Norcodein	Tolbutamide
Diphenhydramine	EDDP	Triamterene
Digoxin	D-Norpropoxyphene	Trifluoperazine
Diphendramine	Ecgonine hydrochloride	Trimethoprim
EMDP	Ecgonine methylester	Trimipramine
EMDP	(-) -Ψ -Ephedrine	Tryptamine
Ecgonine hydrochloride	[1R,2S] (-) Ephedrine	DL-Tryptophan
Ecgonine methylester	(L) - Epinephrine	Tyramine
(-) -Ψ -Ephedrine	Erythromycin	Uric acid
[1R,2S] (-) Ephedrine	β-Estradiol	Verapamil
(L) - Epinephrine		Zomepirac
Erythromycin		
β-Estradiol		

BIBLIOGRAPHY

- Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991; 216
- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
- Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		



ISO



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